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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,721	12/11/2003	Michael Patane	CASM122095	1968
26389 7590 05/21/2007 CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC 1420 FIFTH AVENUE SUITE 2800 SEATTLE, WA 98101-2347			EXAMINER KISHORE, GOLLAMUDI S	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 05/21/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/734,721

Applicant(s)

PATANE, MICHAEL

Examiner

Gollamudi S. Kishore, Ph.D

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 21-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4-5-04; 12-5-05; 12-12-05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election without traverse of Group I claims 1-20 in the reply filed on 4-27-07 is acknowledged.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1- 5, 7-12 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torchillin (US 2005/0163832) in combination with WO 85/04880 of record.

Torchillin discloses liposomal compositions containing DNA for intracellular delivery. The liposomes contain Phosphatidylcholine (PC), cholesterol and a positively charged lipid, DOTAP. PC and cholesterol are in a molar ratio of 7:3 (63:27 molar %). These ratios are above instant percentages. However, The preferred amounts of DOTAP are 0.5 to 10 mol % (0010, 0021, 0026, 0028, 0035, 0040, Example II). What is lacking in Torchillin is the inclusion of phosphatidylethanolamine.

WO 85 while disclosing acid induced liposome fusion method teaches that the presence of phosphatidylethanolamine in the liposomes greatly enhances the fusion. WO also teaches that cholesterol (40 %) greatly decreases the leakage without impairing fusion. The fatty acid taught is oleic acid. The compositions are for the

delivery of molecules such as DNA. The molar percentages for PE: cholesterol: PC as calculated from the values in Table II are 40: 40: 20 (abstract, examples and claims).

To include PE in the compositions in the compositions of Torchillin would have been obvious to one of ordinary skill in the art since it greatly enhances fusion. One of ordinary skill in the art would be motivated to vary the amounts of cholesterol since it does not inhibit the fusion even at 40 %. Similarly to vary the amounts of PC and PE in Torchillin would have been obvious to one of ordinary skill in the art to obtain the best possible results.

4. Claim 1-12 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torchillin (US 2005/0163832) in combination with WO 85/04880 of record as set forth above, further in view of Heath (5,902,802).

The teachings of Torchillin and WO have been discussed above. What is lacking in these references is the teaching of the use of ergo sterol instead of cholesterol.

Heath while disclosing liposomes containing cationic lipids teaches that either ergo sterol or cholesterol could be used in the liposomes in combination with the cationic lipids. The sterol amounts suggested are 0-67 mole percent (col. 6, lines 43-55).

The use of ergo sterol instead of cholesterol in the compositions of Torchillin would have been obvious to one of ordinary skill in the art since Heath teaches that ergo sterol could be used instead of cholesterol. To lower the amounts of cholesterol in Torchillin would have been obvious to one of ordinary skill in the art since Heath teaches that its amounts could be varied from 0 to 67 mole percent.

5. Claim 13-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torchillin (US 2005/0163832) in combination with WO 85/04880 of record or these references further in view of Heath (5,902,802) as set forth above, further in view of Kapeller-Libermann (2002-0081633).

The teachings of Torchillin, WO and Heath have been discussed above. What is lacking in these references is the teaching of encapsulation of a phosphodiesterase.

Kapeller-Libermann while disclosing method of using a cyclic nucleotide phosphodiesterase teaches that delivery systems such as liposomes can be used to deliver phosphodiesterase to cells in vitro as well as in vivo (abstract, 0334 and 0343).

It would have been obvious to one of ordinary skill in the art to encapsulate a phosphodiesterase in the liposomes of Torchillin, WO and Heath with a reasonable expectation of success since Kapeller-Libermann teaches that this enzyme can be encapsulated within liposomes for the delivery to cells in vitro.

6. Claim 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torchillin (US 2005/0163832) in combination with WO 85/04880 of record or further in view of Heath (5,902,802) as set forth above, further in view of Conklin (2002-0156259).

The teachings of Torchillin, WO and Heath have been discussed above. What is lacking in these references is the teaching of encapsulation of a deaminase.

Conklin while disclosing method of using deaminases teaches that delivery systems such as liposomes can be used to deliver a deaminase (abstract, 0287-0292).

It would have been obvious to one of ordinary skill in the art to encapsulate a deaminase in the liposomes of Torchillin, WO and Heath with a reasonable expectation

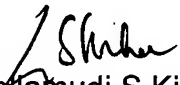
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of success since Conklin teaches that this enzyme can be encapsulated within liposomes for the delivery to cells in vitro.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK